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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,834	STAHL ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 20-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 20-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 10/11/07.

The amendment filed 10/11/07 affects the application, 10/576,834 as follows:

1. Claims 16 and 30 have been amended. New Claims 31-39 have been added.

2. The responsive to applicants' arguments is contained herein below.

Claims 16 and 20-39 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 20-26 and 31-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "and/or human immunodeficiency virus infection" in claim 16 renders the claim indefinite. More specifically, it is unclear whether or not the treatment of human immunodeficiency virus infection is optionally included in "the group consisting of" the said diseases as suggested by the phrase "and/or human immunodeficiency virus infection" or when human immunodeficiency virus infection is included in said group it is unclear what other disease(s) is excluded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 20-26 and 31-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in a mammal, comprising administering the said given oligosaccharide composition, does not reasonably provide enablement for preventing said diseases or conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method for the treatment and or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and

acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of a given specific oligosaccharide composition.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating and/or preventing an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in any mammal by administering a oligosaccharides composition to any mammal.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses the prevention the said diseases or conditions in any mammal, which are not known to have a single recognized cause. Applicants claims are drawn to a method for the prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in a

mammal, comprising administering to said mammal a specific oligosaccharide composition, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said diseases or conditions, which is seen to be lacking a clear description via art recognized procedural and methodological steps. For example, an allergy is an abnormal response by the immune system. Allergies develop because of a mixture of inherited and environmental factors. In addition, the prevention of allergy such as allergy Type 1, allergy Type 2, allergy Type 3 and allergy Type 4 does not have a single recognized cause. For example, Allergies Type 1 which is also called contact allergy (and includes atopy, asthma, hay fever, eczema, food allergy and drug allergy) has several causes which include food, mold, animal dander, pollen, or dust. In fact, the aforementioned allergies are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyle choices such as the diet and maintenance of bodily healthiness which includes (1) genetic predisposition (2) exposition to allergen(s) and (3) family history of said disease. These are only a few of the factors that promote these diseases in people. Similarly, the prevention of immunosenescence, acquired immunodeficiency syndrome and human immunodeficiency virus infection in a mammal comprising administering to said mammal a composition (wherein these said diseases or conditions are characterized as having several causes and contributing factors), is not generally known to exist in this art and is also rejected herein. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented.

Thus, the skilled artisan would view that the prevention of the said diseases or conditions (which is characterized as having many contributing factors and causes) in any mammal by administering to said mammal the specific composition herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary: Moreover, it is noted that the specification does not provide any working examples.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence, acquired immunodeficiency syndrome or human immunodeficiency virus infection in a mammal, comprising administering to said mammal a specific oligosaccharide composition, in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of preventing said diseases or condition of any mammal as recited in the instant claims suitable to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, the prevention allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence, acquired immunodeficiency syndrome or human immunodeficiency virus infection in a mammal, comprising administering to said mammal said specific oligosaccharide composition by said method is not enabled by the instant disclosure. It should

be noted that claims 20-26 and 31-39 which are drawn to a method of preventing the said diseases are also encompassed by the aforementioned rejection.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al. (US 2003/0022863 A1).

In claim 16, applicant claims a method for the treatment and/or prevention of an immune system-related disorder selected from the group consisting of allergy Type 1, allergy Type 2, allergy Type 3, allergy Type 4, immunosenescence and acquired immunodeficiency syndrome and/or human immunodeficiency virus infection in a mammal, comprising administering to said mammal a composition comprising a therapeutically effective amount of an acid oligosaccharide

and a neutral oligosaccharide, wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooliogosaccharides and mixtures thereof. Claims 20-24, 31-39 are drawn to the said method wherein acid and neutral oligosaccharides are of specific types, wherein the immune system-related disorder is a specific type including allergy types, wherein said method further comprises administering specific polyunsaturated fatty acid per day and wherein the composition comprises specific ingredients and are in specific food forms. Claims 25-26 are drawn to the said method wherein the composition is administered enterally and to humans of specific ages.

Stahl et al. disclose that the adhesions of pathogens, as well as of cell damaging substance on the surface of mammal cells which is an indispensable requisite for an infection (an immune system-related disorder) or a damage of the cell (e.g., inflammation of the skin cells an in an allergic reaction due to pathogens) can be prevented by their composition which comprises an acid oligosaccharide (oligogalactouronide) and a neutral oligosaccharide (galactooligosaccharides or inulin (an oligofructose), wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the neutral oligosaccharide (see page1, section [0002], page 2, section [0023] and page 5, example 8 sections [0054] to [0057]). Furthermore, Stahl et al. disclose that the pathogens include at least bacteria, viruses, fungi, monocellular or multicellular parasites, toxins and heavy-metal cations (see page1, section [0002]). This implies that infections such as bacterial, fungal, viral and

parasitic infections (i.e., immune system related disorder) can be prevented or treated by the use of their composition. In addition, Stahl et al. disclose that their composition can be used for treating infections of the gastrointestinal tract, the blood system, the respiratory passages, the urogenital tract, and the nasopharyngeal meatus, and for treating damages of the cells of the gastrointestinal tract, the blood system, the respiratory passages, the urogenital tract, and the nasopharyngeal meatus caused by toxins or heavy-metal cations (see claim 16). Also, Stahl et al. disclose that their composition is a dietetic (food) composition in that it contains usual food ingredients and food components, including vitamins and trace elements (see claim 13 and claim 1).

The difference between applicant's claimed method and the method suggested by Stahl et al. is that Stahl et al.'s do not exemplify the administration of the their composition for preventing or treating an immune system-related disorder in a mammal. However Stahl et al. suggest that their composition could be administered to said mammal to prevent or treat an immune system-related disorder (pathogen infections) or a damage of the cell (which includes inflammation of the skin cells an in an allergic reaction due to pathogens).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Stahl et al. to administer Stahl et al.'s antiadhesive composition to prevent or treat an immune system-related disorder (such as pathogen infections) or a damage of the cell (which includes inflammation of the skin cells an in an allergic type reactions due to pathogens) in a mammal, since Sthal et al.'s suggest that their composition can be used to prevent or treat the same said conditions.

One having ordinary skill in the art would have been motivated to use the method suggested by Stahl et al. to administer Stahl et al.'s antiadhesive composition to treat an immune system-related disorder (such as a pathogen infection) or a damage of the cell (which includes inflammation of the skin cells an characterized in an allergic type reactions due to pathogens) in a mammal, since a skilled artisan would reasonable expect to use the composition taught by Stahl et al. for the same said purpose. It should be noted that the use of specific routes of administration such as enteral administration depends on factors such as the severity and location of the condition or disorder treated, the type, age and size of mammal. Also, it should be noted that the use specific food compositions, is also encompassed by this rejection since applicant's composition contains the same oligosaccharides and since the preparation of food compositions including the food composition suggested by Stahl et al. is common in the art and is well within the purview of a skilled artisan and depends on factors such as the type, age of the individuals to whom the composition is be administered.

Claim 27 is drawn to a food composition comprising specific % of lipid, protein, carbohydrate, acid oligosaccharide and neutral oligosaccharide, wherein said acid oligosaccharide comprises at least one terminal uronic acid unit, has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and said neutral oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins, galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooligosaccharides and mixtures thereof. Claims 28 and 29 are drawn to the food composition of claim 27 having specific caloric density and viscosity. Claim 30 is drawn to a liquid composition comprising fat,

carbohydrate, protein and specific amounts of soluble indigestible oligosaccharides (neutral oligosaccharides) and acid oligosaccharides.

Stahl et al. disclose a dietetic composition comprising an acid oligosaccharide (oligogalactouronide) and a neutral oligosaccharide (galactooligosaccharides or inulin (an oligofructose), wherein: the acid oligosaccharide has a degree of polymerization between 1 and 250 and is prepared from pectin or alginate; and the neutral oligosaccharide (see page1, section [0002], page 2, section [0023] and page 5, example 8 sections [0054] to [0057]). Furthermore, Stahl et al. disclose that their composition is a dietetic (food) composition in that it contains usual food ingredients and food components, including vitamins and trace elements (see claim 13 and claim 1). In addition, Sthal et al.'s disclose that their composition has antiadhesive effect in that it can reduce and/or block the adhesion of pathogenic substances and organisms to eucaryontic cells, in particular mammal cells (see abstract).

The difference between applicant's composition and the composition of Stahl et al. is that Stahl et al.'s do not exemplify a specific food or dietetic composition which contains usual or common food ingredients and food components.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the food (dietetic) composition suggested by Stahl et al. and to include the usual food ingredients or components such as lipids, proteins and carbohydrates in different percentages in order to use it as an antiadhesive, since Sthal et al.'s disclose that their composition can be used to an antiadhesive to for reducing and/or blocking the adhesion of pathogenic substances and organisms to eucaryontic cells, in particular mammal cells.

One having ordinary skill in the art would have been motivated to prepare the food (dietetic) composition suggested by Stahl et al. and to include the usual food ingredients or components such as lipids, proteins and carbohydrates in different percentages in order to use it as an antiadhesive, since a skilled artisan would reasonable expect to use the composition taught by Stahl et al. for the same said purpose. It should be noted that the preparation of food compositions of specific caloric content and viscosity depends on factor such as type, age of the individuals to whom the composition is be administered. Also, it should be noted that claim 30 which is drawn to a liquid composition (a liquid food), is also encompassed by this rejection since applicant's composition contains the same oligosacchrides and since the preparation of a liquid form a composition such as the food composition suggested by Stahl et al. is common in the art and is well within the purview of a skilled artisan and depends on factors such as the type, age of the individuals to whom the composition is be administered.

Response to Arguments

Applicant's amendments have not overcome the enablement rejections pertaining to prevention of the specifically recited diseases by administering said oligosaccharide composition, as set forth above.

Applicant's arguments with respect to claims 16 and 20-39 have been considered but are not found convincing.

The applicant argues that according to the Office Action, Stahl does not teach "the administration of their composition for preventing or treating an immune system-related disorder in a mammal." (Office Action at page 8). However, the office action states that Stahl et al. "do not exemplify the administration of their composition for preventing or treating an immune

system-related disorder in a mammal. However, Stahl et al. suggest that their composition could be administered to said mammal to prevent or treat an immune system-related disorder (pathogen infections) or a damage of the cell (which includes inflammation of the skin cells an in an allergic reaction due to pathogens) (see also the above rejection).

The applicant argues that a skilled artisan would not instantly and unquestionably know that this preparation also increases Thl and decrease Th2 responses, or is suitable as a method of treating and/or preventing the claimed immune system-related disorders. However, the rejections set forth above are not based on the effects of the composition or preparation with respect to increasing Thl and decreasing Th2 responses (which are not claimed by applicant). That is, a determination of said effects is not a required or necessary suggestion or motivation for a skilled artisan, as set forth in above rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 15, 2008

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